IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Susumu SHIOMI Appl. No.: 10/596,945 (*U.S. National Stage of PCT/JP2004/018643; I.A. Filed: December 14, 2004*) For: **Preventive Agent for Carcinogenesis of Liver Cancer Containing Quinone-Based Compound as Active Ingredient** (as amended)	Confirmation No.: 2732 Art Unit: *To be assigned* Examiner: *To be assigned* Atty. Docket: 1089.0600000/MAC/DJN

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Mail Stop PCT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents **FP1** to **FP4** and **NPL1** to **NPL29** are submitted. In accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents, documents **US1** and **US2**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicant's undersigned representative submits the following discussion of the relevance of the non-English language documents **FP1**, **FP2**, **FP3**, **FP4**, **NPL3**, **NPL4**, **NPL8**, **NPL11**, **NPL13**, **NPL15**, **NPL21**, and **NPL24** cited on Forms PTO/SB/08A and PTO/SB/08B:

Document **FP1**, JP 49-55650, is in the Japanese language. The disclosure is directed to a process for producing vitamin K2. More specifically, the process disclosed

in this publication comprises oxidizing dihydrovitamin K2 with lead peroxide, wherein acetic acid is present in this oxidizing step.

Document **FP2**, JP 63-185921, is in the Japanese language. An English language abstract of document FP2 is attached as document **NPL26**. According to the abstract, the disclosure relates to a remedy for hepatic disease by using a quinone derivative or its hydroquinone compound as an active component. The abstract further provides that the compound has strong 5-lipoxygenase-inhibiting and antioxidation effects and low toxicity and is useful for the prevention and remedy of chronic hepatitis, fulminant hepatitis, hepatofibrosis, hepatocirrhosis, alcoholic hepatitis, etc.

Document **FP3**, JP 06-305955, is in the Japanese language. An English language abstract of document FP3 is attached as document **NPL27**. According to the abstract, the disclosure relates to menatetrenone as an active ingredient, having cell differentiation inducing action and useful for treating tumors of hematopoietic organs, solid tumors, etc. The abstract further provides that menatetrenone is well known as a hemostatic vitamin and clinically widely used as a medicine with hardly any side effects, has high safety and further cell differentiation inducing action and can be formulated into a dosage form such as an oral agent, a parenteral injection or an external percutaneous agent. The daily dose is 10 mg to 1 g, preferably 100 mg to 1 g for an adult. The abstract further provides that the inducer is useful for tumors of hematopoietic organs such as acute leukemia, chronic leukemia, malignant lymphoma, multiple myeloma, or macroglobulinemia and solid tumors such as cerebral tumor, head and neck cancer, mammary cancer, lung cancer, esophageal carcinoma, gastric cancer, carcinoma of the colon, cancer of the liver, gallbladder and bile duct cancer, cancer of the pancreas, islet cell cancer, renal cell carcinoma, adrenocortical cancer, baldder cancer, prostatic cancer, testicular tumor,

ovarian cancer, urterine cancer, villous cancer, thyroid cancer, malignant carcinoid tumor, carcinoma cutaneum, malignant melanoma or osteosarcoma.

Document **FP4**, WO 03/105819 A1, is in the Japanese language. An English language abstract of document FP4 is attached as document **NPL28**. Document **FP4**, was cited in the International Search Report by a foreign patent office during the International Stage of this application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided as document **NPL29** in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

Document **NPL3**, Ichida, F., *et al.*, "Clinical evaluation of human lymphoblastoid interferon (OPC-18) in patients with inactive chronic hepatitis C - A randomization study to find the optimal duration of treatment," *Kantansui 32*:101-127, (1996), is in the Japanese language. In this article, the researchers have investigated effectiveness and safety of OPC-18 on chronic inactive hepatitis and chronic persistent hepatitis with administration of 500 million IU/day for 16 weeks and 24 weeks. According to the results, improvement of hepatic function was confirmed in terms of GPT value (Table 5), GOT value (Table 5), γ-GTP (Table 5), total bilirubin (Table 5), serum albumin (Table 5) and the like. The improvement was 28.9% for the 16 week administration group, and 46.4% for the 24 week administration group. Thus, there was significantly higher improvement for the 24 week administration group than for the 16 week administration group (See Tables 6 to 8). However, it was reported in this article that interferon has the problem with side effects of interstitial pneumonia, depression and diabetes.

Document **NPL4**, Ikeda, K. and Kumada, H., "Clinical significance of long-term natural course of and treatment of chronic hepatitis C liver disease," *Kanzo 35*:772-773,

Nihon Kanzo Gakkai (1994), is in the Japanese language. The researchers have investigated whether interferon can inhibit the progress of chronic hepatitis C liver disease, and whether interferon can inhibit the transfer from liver cirrhosis to carcinogenesis of liver cancer in terms of the long-term observation. Fig. 1 shows the progress rate to cirrhosis from chronic hepatitis type C can be inhibited by interferon. On the other hand, Fig. 2 shows that cumulative percentage of carcinogenesis in type C liver cirrhotic patients within 5 years is 27%, within 10 years is 52.4%, and within 15 years is 70.6%.

Document **NPL8**, Koike, Y., *et al.*, "A Randomized Controlled Study by Vitamin K-II Injection for the Purpose of Preventing Portal Venous Invasion (PVI)," *Kanzo 43(suppl.1)*:A64, abstract no. O-98, Nihon Kanzo Gakkai (2002), is in the Japanese language. An unverified English language translation of document NPL8 is attached as document **NPL9**. Document **NPL8** was cited in the International Search Report by a foreign patent office during the International Stage of this application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided as document **NPL29** in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

Document **NPL11**, Mizuta, T., *et al.*, "A Clinical Study of the Effects of Vitamin K in Inhibiting Recurrence of Hepatocellular Carcinoma," *Jpn. J. Gastroenterol. 99*:A192, abstract no. 308, Gastroenterological Association of Japan (2002), is in the Japanese language. An unverified English translation of document NPL11 is attached as document **NPL12**.

Document **NPL13**, Mizuta, T., *et al.*, "Inhibitory effect of vitamin K injection against the recurrence of hepatocellular carcinoma," *38th Annual Meeting of Liver*

Cancer Study Group of Japan, pg. 135, abstract no. 110, (2002), is in the Japanese language. An English language translation of document NPL13 is attached as document **NPL14**.

Document **NPL15**, Mizuta, T. and Yamamoto, K., "Vitamin K2 agent to inhibit recurrence of hepatic cancer," *J. Ther. 85*:1554-1555, Tōkyō (April, 2003), is in the Japanese language. Hepatocellular carcinoma develops in the background of the chronic hepatic disease. After the basic remedy for hepatocellular carcinoma, the recurrence of hepatocellular carcinoma has been observed in the remaining liver. To improve the prognosis of hepatocellular carcinoma, it is important to inhibit the recurrence of hepatocellular carcinoma. Vitamin K2 (hereinafter referred to as "VK2") is widely used as a therapeutic agent for osteoporosis clinically. Also, VK2 is known to have inhibitive action for proliferation of various tumor cells including leukemia cells and hepatic cancer cells, and to have inductive action for apoptosis and differentiation. The researchers have clinically investigated the recurrence inhibitive effects of VK2 on the post-treatment of hepatocellular carcinoma. FIG. 1 illustrates graph indicating the effects of VK2 administration on hepatic cancer recurrence inhibition. As can be seen from FIG. 1, it was confirmed that risk of the recurrence after treatment of hepatocellular carcinoma was reduced by administrating VK2.

Document **NPL21**, Yamaoka *et al.*, Liver Cancer Study Group of Japan, "Survey and Follow-up study of primary liver cancer in Japan, Report 14," *Kanzo 29*:799-811, Nihon Kanzo Gakkai (2000), is in the Japanese language. An English language abstract of document NPL21 is attached as document **NPL22**. Document **NPL21** was cited in the International Search Report by a foreign patent office in the International Stage of this application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided as document

NPL29 in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

Document **NPL24**, Russian Official Action for Russian Application No. 2004136304/15(039482), Russian Patent and Trademark Office, dated March 29, 2006, is in the Russian language. An unverified English language translation of document NPL24 is attached as document **NPL25**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Daniel J. Nevrivy
Agent for Applicant
Registration No. 59,118

Date: January 18, 2007

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

550331_1.DOC

Equivalent of Form PTO/SB/08A (07-05)
Approved for use through 07/31/2006.
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/596,945
Filing Date	December 14, 2004
First Named Inventor	Susumu SHIOMI
Art Unit	*To be assigned*
Examiner Name	*To be assigned*
Attorney Docket Number	1089.0600000/MAC/DJN

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (If Known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	5,021,570	06/04/1991	Ida *et al.*	
	US2	7,138,433	11/21/2006	Koike *et al.*	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	JP 49-55650	05/30/1974	Eisai Co., Ltd.		
	FP2	JP 63-185921	08/01/1988	Takeda Chem. Ind. Ltd.		Abs
	FP3	JP 06-305955	11/01/1994	Eisai Co., Ltd.		Abs
	FP4	WO 03/105819 A1	12/24/2003	Eisai Co., Ltd.		Abs

550049v1

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08B (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	10/596,945
Filing Date	December 14, 2004
First Named Inventor	Susumu SHIOMI
Art Unit	*To be assigned*
Examiner Name	*To be assigned*
Attorney Docket Number	1089.0600000/MAC/DJN

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T[2]
	NPL1	Furukawa, M., *et al.*, "Changes of Plasma Des-γ-Carboxy Prothrombin Levels in Patients With Hepatocellular Carcinoma in Response to Vitamin K," *Cancer 69*:31-38, J.B. Lippincott Company (1992)	
	NPL2	Habu, D., *et al.*, "Role of Vitamin K_2 in the Development of Hepatocellular Carcinoma in Women With Viral Cirrhosis of the Liver," *JAMA 292*:358-361, American Medical Association (July 2004)	
	NPL3	Ichida, F., *et al.*, "Clinical evaluation of human lymphoblastoid interferon (OPC-18) in patients with inactive chronic hepatitis C - A randomization study to find the optimal duration of treatment," *Kantansui 32*:101-127, ArcMedium (1996)	
	NPL4	Ikeda, K. and Kumada, H., "Clinical significance of long-term natural course of and treatment of chronic hepatitis C liver disease," *Kanzo 35*:772-773, Nihon Kanzo Gakkai (1994)	
	NPL5	Johnson, J.I., *et al.*, "Relationships between drug activity in NCl preclinical in vitro and in vivo models and early clinical trials," *Brit. J. Canc. 84*:1424-1431, Nature Publishing Group on behalf of Cancer Research UK (2001)	
	NPL6	Koike, Y., *et al.*, "Des-γ-Carboxy Prothrombin As a Useful Predisposing Factor for the Development of Portal Venous Invasion in Patients with Hepatocellular Carcinoma," *Cancer 91*:561-569, John Wiley & Sons, Inc. (2001)	
	NPL7	Koike, Y., *et al.*, "Randomized Prospective Study of Prevention from Tumor Invasion into Portal Vein in 120 Patients with Hepatocellular Carcinoma by Vitamin K Administration," available online at http:ddw02.agora.com/planner/displayabstract.asp?presentationid=31, Abstract ID 105864, 1 page (2002)	
	NPL8	Koike, Y., *et al.*, "A Randomized Prospective Controlled Study by Vitamin K-II Injection for the Purpose of Preventing Portal Venous Invasion (PVI)," *Kanzo 43(suppl.1)*:A64, abstract no. O-98, Nihon Kanzo Gakkai (2002)	Yes
	NPL9	Unverified English language translation of Koike, Y., *et al.*, "A Randomized Prospective Controlled Study by Vitamin K-II Injection for the Purpose of Preventing Portal Venous Invasion (PVI)," *Kanzo 43(suppl.1)*:A64, abstract no. O-98, Nihon Kanzo Gakkai (2002)	

550251v1

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				***Complete if Known***	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	10/596,945
				Filing Date	December 14, 2004
				First Named Inventor	Susumu SHIOMI
				Art Unit	*To be assigned*
				Examiner Name	*To be assigned*
Sheet	2	of	3	Attorney Docket Number	1089.0600000/MAC/DJN

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T[2]
	NPL10	Li, Z.-Q., *et al.*, "Vitamin K uptake in hepatocytes and hepatoma cells," *Life Sci. 70*:2085-2100, Elsevier Science Inc. (2002)	
	NPL11	Mizuta, T., *et al.*, "A Clinical Study of the Effects of Vitamin K in Inhibiting Recurrence of Hepatocellular Carcinoma," *Jpn. J. Gastroenterol. 99*:A192, abstract no. 308, Gastroenterological Association of Japan (2002)	Yes
	NPL12	Unverified English language translation of Mizuta, T., *et al.*, "A Clinical Study of the Effects of Vitamin K in Inhibiting Recurrence of Hepatocellular Carcinoma," *Jpn. J. Gastroenterol. 99*:A192, abstract no. 308, Gastroenterological Association of Japan (2002)	
	NPL13	Mizuta, T., *et al.*, "Inhibitory effect of vitamin K injection against the recurrence of hepatocellular carcinoma," *38th Annual Meeting of Liver Cancer Study Group of Japan*, pg. 135, abstract no. 110, (2002)	Yes
	NPL14	Unverified English language translation of Mizuta, T., *et al.*, "Inhibitory effect of vitamin K injection against the recurrence of hepatocellular carcinoma," *38th Annual Meeting of Liver Cancer Study Group of Japan*, pg. 135, abstract no. 110, (2002)	
	NPL15	Mizuta, T. and Yamamoto, K., "Vitamin K2 agent to inhibit recurrence of hepatic cancer," *J. Ther. 85*:1554-1555, Tōkyō (April 2003)	
	NPL16	Nishiguchi, S., *et al.*, "Randomised trial of effects of interferon-α on incidence of hepatocellular carcinoma in chronic active hepatitis C with cirrhosis," *Lancet 346*:1051-1055, Lancet Publishing Group (1995)	
	NPL17	Ohizumi, H., *et al.*, "Geranylgeraniol Is a Potent Inducer of Apoptosis in Tumor Cells," *J. Biochem. 117*:11-13, Oxford University Press (1995)	
	NPL18	O'Neil, J.M., *et al.*, eds., "Vitamin K," in: *The Merck Index*, 13th Ed., Merck & Co., Inc., Rahway, NJ, page 1787, item 10082, (2001)	
	NPL19	Wang, Z., *et al.*, "The Growth Inhibitory Effects of Vitamins K and Their Actions on Gene Expression," *Hepatol. 22*:876-882, John Wiley & Sons, Inc. (1995)	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	10/596,945
				Filing Date	December 14, 2004
				First Named Inventor	Susumu SHIOMI
				Art Unit	*To be assigned*
				Examiner Name	*To be assigned*
Sheet	3	of	3	Attorney Docket Number	1089.0600000/MAC/DJN

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T[2]
	NPL20	Wu, F.Y.-H., *et al.*, "Comparison of Antitumor Activity of Vitamins K_1, K_2, and K_3 on Human Tumor Cells by Two (MTT and SRB) Cell Viability Assays," *Life Sci. 52*:1797-1804, Pergamon Press (1993)	
	NPL21	Yamaoka, Y., *et al.*, Liver Cancer Study Group of Japan, "Survey and Follow-up study of primary liver cancer in Japan, Report 14," *Kanzo 41*:799-810, Nihon Kanzo Gakkai (2000)	Abs
	NPL22	English language abstract of Yamaoka, Y., *et al.*, Liver Cancer Study Group of Japan, "Survey and Follow-up study of primary liver cancer in Japan, Report 14," *Kanzo 41*:799-810, Nihon Kanzo Gakkai (2000)	
	NPL23	STN Database, Registry No. 863-61-6, "1,4-Naphthalenedione, 2-methyl-3-[(2E,6E,10E)-3,7,11,15-tetramethyl-2,6,10,14-hexadecatetraenyl" (1984)	
	NPL24	Copy of Russian Official Action for Russian Application No. 2004136304/15(039482), Russian Patent and Trademark Office, dated March 29, 2006	Yes
	NPL25	Unverified English language translation of Russian Official Action for Russian Application No. 2004136304/15(039482), Russian Patent and Trademark Office, dated March 29, 2006	
	NPL26	Patent Abstracts of Japan, English language abstract for JP 63-185921	
	NPL27	Patent Abstracts of Japan, English language abstract for JP 06-305955	
	NPL28	Dialog File 351, Accession No. 15924220, WPI English language abstract of WO 03/105819 (listed on accompanying PTO/SB/08A as document FP4)	
	NPL29	Copy of International Search Report for International Patent Application No. PCT/JP2004/018643, mailed April 19, 2005, Japanese Patent Office, Japan	

550251v1

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.